

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Daopei LU

Title: ARSENIC SULFIDE COMPOUNDS AND  
DERIVATIVES THEREOF FOR THE  
TREATMENT OF MALIGNANCIES

Appl. No.: 10/635,653

Filing Date: 8/7/2003

Examiner: Pryor, Alton Nathaniel

Art Unit: 1616

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicant submits herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/110,366, filed 7/6/1998. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

04/23/2004 EAREGAY1 00000013 10635653

01 FC:1806

180.00 DP

002.1187776.1

APR 22 2004

U.S. PATENT & TRADEMARK OFFICE  
RECEIVED  
APR 22 2004

### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

### RELEVANCE OF EACH DOCUMENT

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

### FEE

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 22 April 2004

By S. A. Bent

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: April 22, 2004

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/635,653
Filing Date	8/7/2003
First Named Inventor	Daopei LU
Group Art Unit	1616
Examiner Name	Pryor, Alton Nathaniel

Attorney Docket Number 077319-0373

Sheet

1

of

8

APR 22 2004

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,720,011		Zhang	4/13/04	
		US 2002-0183385		Ellison et al.	12/5/02	
		132,275		Gettins	10/15/1872	
		232,807		Dennett	10/05/1886	
		3,700,498		Kanazawa et al.	10/24/72	
		4,497,780		Barin et al.	2/05/85	
		5,759,837		Kuhajda et al.	6/2/98	
		US 2002 0013371		Warrell, Jr. et al.	1/31/02	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		CN	1061908 A		Yang et al.	6/17/92		
		CN	1079391 A			12/15/93		
		JP	51-88620			3/8/76		
		WO	95/01789			1/19/95		
		CN	1133725 A			10/23/96		
		CN	1131037 A			9/18/96		
		CN	1122700 A			5/22/96		
		CN	1081104 A			1/26/94		
		CN	1119113 A			3/27/96		
		CN	1121807 A			5/8/96		
		WO	94/02108			2/3/94		
		FR	2 539 993 A1			3/31/94		
		DE	43 17 331 A1			12/1/94		
		WO	95/22336			8/24/95		
		LV	11667 B			6/20/97		
		DE	2 539 993			3/31/94		

Examiner Signature:

Date Considered:

\*EXAMINER: Initial if reference considered. Whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/635,653
Date Submitted: April 22, 2004 <i>(use as many sheets as necessary)</i>				<b>Filing Date</b>	8/7/2003
				<b>First Named Inventor</b>	Daopei LU
				<b>Group Art Unit</b>	1616
				<b>Examiner Name</b>	Pryor, Alton Nathaniel
Sheet	2	of	8	<b>Attorney Docket Number</b>	077319-0373

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
		"Diarsendisulfid As <sub>2</sub> S <sub>2</sub> ", Gmelin's Arsenic, 8 <sup>th</sup> Edition, 17:417-422, 1952		
		"Arsen (III)-Sulfid As <sub>2</sub> S <sub>2</sub> ", Gmelin's Arsenic, 8 <sup>th</sup> Edition, 17:422-433, 1952		
		Qi and Bi, "Method for removing As <sub>2</sub> O <sub>3</sub> from Realgar", Chung Yao Tung Pao, 8(5):21-22, 1983		
		"Letter on Historical Facts Regarding the Development of Ai Ling No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of its Mechanism," Heilongjiang Branch of the Chinese Medical Association, March 27, 1998.		
		Wang et al., "Arsenic Trioxide and Melarsoprol Induced Programmed Cell Death in Myeloid Leukemia Cell Lines and Function in a PML and PML-PAR $\alpha$ Independent Manner," Blood, 92(5):1497-1504, 1998.		
		Yuan et al., Journal of Traditional Chinese Medicines, Vol. 13(8), August 1988		
		Zhang et al., "Discussion on methods for removing As involving use of yogurt", Zhongguo Zhongyao Zaahi, 20(9): 537, 1995		
		Yuan et al., "Exploring methods for purifying Realgar", Chung Yao Tung Pao, 13(8): 17-21, 1988		
		Yuan et al., "Research on traditional methods for Purifying Realgar", Chung Yao Tung Pao, 13(8); 23-26, 1988		
		"Realgar", Chinese Pharmacopia (I), Guangdong Science and Technology Publishing House, China, pp 298-299, 1995		
		Lu et al., "Effective treatment of AML-M3 (APL) and their remission maintenance with Realgar: A pilot clinical laboratory study on 38 patients", Blood, 90(10 Suppl. 1, part 1), p. 416a, #1849, 1997		
		Forkner et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour. A.M.A., Vol. 97, No. 1, pp. 3-5, 1931		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered; whether or not citation is in conformance with MPEP<sup>2</sup> 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/635,653
Date Submitted: April 22, 2004				<b>Filing Date</b>	8/7/2003
(use as many sheets as necessary)				<b>First Named Inventor</b>	Daopei LU
				<b>Group Art Unit</b>	1616
				<b>Examiner Name</b>	Pryor, Alton Nathaniel
Sheet	3	of	8	Attorney Docket Number	077319-0373

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Stephens et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", Ann. Intern. Assoc. , Vol. 9, 1488-1502, 1936	
		Monfardini et al., "Survival in chronic myelogenous leukemia: influence of treatment and extent of disease at diagnosis", Cancer, 31: 492-501, 1973	
		Cuzick et al., "Medicinal arsenic and internal malignancies", Br. J. Cancer, 45: 904-911, 1982	
		Lee et al., "Induction of gene amplification by arsenic", Science, 241: 79-81, 1988	
		Wang et al., "Studies on chemically preventing leukemia", Chung Hua Chung Liu Tsa Chih, 11(3); 207-210, 1989	
		Pershagen et al., "On the pulmonary tumorigenicity of arsenic trisulfide and calcium arsenate in hamsters", Cancer Letters, 27: 99-104, 1985	
		Yamamoto et al., Tumorigenicity of inorganic arsenic compounds following intratracheal instillations to the lungs of hamsters", Int. J. Cancer, 40:220-223, 1987	
		Andre et al., "The PML and PLM/RAR $\alpha$ Domains: from autoimmunity to molecular oncology and from retinoic acid to arsenic", Experimental Cell Research 229: 253-260, 1996	
		Schenk, Handbook of Preparative Inorganic Chemistry, 1: 603, G. Brauer, Ed., Academic press, New York, 2 <sup>nd</sup> Ed., 1963	

Examiner Signature		Date Considered
--------------------	--	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: April 22, 2004

(use as many sheets as necessary)

Sheet

4

of

8

**Complete if Known**

Application Number 10/635,653

Filing Date 8/7/2003

First Named Inventor Daopei LU

Group Art Unit 1616

Examiner Name Pryor, Alton Nathaniel

Attorney Docket Number 077319-0373

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Mervis, "Ancient remedy performs new tricks", Science, Vol. 273: 578, 2 August, 1996	
		Chemical Abstract, 63-Pharmaceuticals, Vol. 11, pp. 317, #111: 219272j and 111: 219276p, 1987-1991	
		Lu et al., "Study of Realgar in the treatment of acute promyelocytic Leukemia (APL)- a pilot clinical and laboratory study on 32 patients, China-Korea Medical Conference '97, 1997	
		Dictionary of Inorganic Compounds, Vol. 1, Ac-C <sub>10</sub> , IC-000667-IC-000671	
		Germolec et al., "Arsenic induces over expression of growth factors in human keratinocytes", toxicology And Applied Pharmacology, 141:308-318, 1996	
		Shen et al., "Use of arsenic trioxide (AS <sub>2</sub> -O <sub>3</sub> ) in the treatment of acute promyelocytic Leukemia (APL): II. Clinical efficacy and pharmacokinetics in relapsed patients", Blood, Vol. 89, No. 9, pp. 3354-3360, May 1, 1997	
		Chen et al., "In vitro studies on cellular and molecular mechanisms of arsenic trioxide (AS <sub>2</sub> -O <sub>3</sub> ) in the treatment of acute promyelocytic Leukemia (APL): AS <sub>2</sub> -O <sub>3</sub> includes NB4 cell apoptosis with down regulation of Bcl-2 expression and modulation of PML-RAR $\alpha$ /PML proteins", Blood, Vol. 88, No. 3, pp. 1052-1061, August 1, 1996	
		Kasper et al., "Hepatic Angiosarcoma and bronchioloalveolar carcinoma induced by Fowler's solution", JAMA, Vol. 252, No. 24, pp. 3407-3408, 1984	
		Cutler et al., Article IV, American Journal of the Medical Sciences, pp. 74-84	

Examiner  
Signature\*Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/635,653
Date Submitted: April 22, 2004				<b>Filing Date</b>	8/7/2003
(use as many sheets as necessary)				<b>First Named Inventor</b>	Daopei LU
				<b>Group Art Unit</b>	1616
				<b>Examiner Name</b>	Pryor, Alton Nathaniel
Sheet	5	of	8	Attorney Docket Number	077319-0373

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Neubauer, "Arsenic Cancer: a review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947.	
		Zhu et al., "Arsenic-induced PML targeting onto nuclear bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci., Vol. 94, pp. 3978-3983, April 1997	
		Hutchinson, "IX. Diseases, Etc., of the skin."	
		"Goodman & Gilman's The pharmacological basis of therapeutics", ninth edition, McGraw-Hill, Health Professions Division, pp. 1659-1662.	
		Huang, Shiling; Guo, Aixia; Xiang, Yang et al. 1995, "The Linic Study of QUINGDAI Tablet for Treating Acute Promyelocytic Leukemia", China Magazine of Hematology, 16(1):26	
		Xiang, Yang; Huang, Shiling; Guo, Aixia et al., 1995, "60 Cases of Treating Acute Promyelocytic Leukemia by QUINGDAI tablet," Medical Magazine of the Liberation Army, 20(3):227-229	
		"Inorganic Arsenic Compounds Other than Arsine Health and Safety Guide, Health and Safety Guide No. 708", WHO, Geneva, 1992.	
		"Xionghuang", Chinese Pharmacopia (I), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995.	
		Akao et al., "Arsenic Induces Apoptosis in B-cell Leukaemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102:1055-1060, 1998.	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/635,653
Date Submitted: April 22, 2004				<b>Filing Date</b>	8/7/2003
(use as many sheets as necessary)				<b>First Named Inventor</b>	Daopei LU
Sheet	6	of	8	<b>Group Art Unit</b>	1616
				<b>Examiner Name</b>	Pryor, Alton Nathaniel
				<b>Attorney Docket Number</b>	077319-0373

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Arsenic, Environmental Health Criteria 18, Geneva: WHO 1981	
		Chen et al., "Use of Arsenic Trioxide (AS <sub>2</sub> -O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL): I. AS <sub>2</sub> -O <sub>3</sub> Exerts Dose-Dependent Dual Effects on APL Cells", Blood, Vol. 89, No. 9, pp. 3345-3353, 1997	
		Chung et al. "Influence for Carcinoma Cell and Lymphatic cell of Acetyl Arsonate", Yakhak Hoeji Vol. 40, No. 5, pp. 599 -607, 1996	
		de Thé, "L'oxyde d'arsenic: après l'acide rétinoïque, un nouveau traitement ciblé de la leucémie aiguë promyélocytaire", médecine/sciences; 13:867-71, 1997	
		Flamigni et al., "Effect of Sodium Arsenite on the Induction and Turnover of Ornithine Decarboxylase Activity in Erythroleukemia Cells", Cell Biochemistry and Function, Vol. 7:213-217, 1989	
		Fluke 1995/96 Catalog, p. 152-153, July 1995.	
		Ishinishi N. et al., "Study on Chronic Toxicity of Arsenic Trioxide in Rats with a Special Reference to the Liver Damages", Fukuok Acta Medicine, 71:27, 1980	
		König et al., "Comparative Activity of Melarsoprol and Arsenic trioxide in Chronic B-Cell Leukemia Lines", Blood, Vol. 90, No. 2, pp. 562-570, July 15, 1997	
		Kwong et al., Delicious Poison: Arsenic Trioxide for the treatment of Leukemia", Blood 89-3487-8, May 1997	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with 37 CFR 1.56. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia, 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: April 22, 2004

(use as many sheets as necessary)

**Complete if Known**

Application Number 10/635,653

Filing Date 8/7/2003

First Named Inventor Daopei LU

Group Art Unit 1616

Examiner Name Pryor, Alton Nathaniel

Sheet 7 of 8 Attorney Docket Number 077319-0373

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Li et al., "Traditional Chinese and Western Medicine in the treatment of 27 Patients with Malignant Lymphoma", Chinese J Oncology, 10:61-62, 1988	
		Pories et al., "Trace Elements that Act to Inhibit Neoplastic growth", Annals New York Academy of Sciences, 199:pp 265-273, 1972	
		Reichl et al., "Effect of Arsenic on Cellular Metabolism after single or Repeated Injection in Guinea Pigs", Arch Toxicol., Suppl 13, p. 363-65, 1989.	
		Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA p. 1570-80, 1990.	
		Shibuya, "Studies on Experimental Arsenious Acid Poisoning", Tokyo Jikeikai Ika Daigaku Zasshi, Vol. 86, No. 4, P. 653, 1971	
		Soignet et al., Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine, Vol. 339, No. 19, November 5, 1988	
		Suehiro Shimotsuura et al., Studies on the Antineoplastic Actions of AS <sub>2</sub> -O <sub>3</sub> ", Shikwa Gakuho 86: 1237-1253, 1986.	
		Sun et al., "Ai Ling #1 and Traditional Chinese Medicine in the Treatment of 32 patients with Acute Promyelocytic Leukemia", Chinese J of Traditional Chinese and Western Medicine, Vol. 12, No. 3, 1992	
		Treleaven et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, Vol. 10, pp. 343-345, 1993	

Examiner Signature:

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/635,653
Date Submitted: April 22, 2004 <i>(use as many sheets as necessary)</i>				<b>Filing Date</b>	8/7/2003
				<b>First Named Inventor</b>	Daopei LU
				<b>Group Art Unit</b>	1616
				<b>Examiner Name</b>	Pryor, Alton Nathaniel
Sheet	8	of	8	Attorney Docket Number	077319-0373

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		USP Dictionary of USAN and International Drug Names, United States Pharmacopeia Conventions, Inc., Rockville, MD, p. 59, November 1994	
		Wang et al., "Arsenic and the Treatment of Leukemia", J Harbin Medical Univ., Vol. 31, No. 5, October 1997	
		Zhang et al., "Traditional Chinese and Western Medicine in the Treatment of 27 patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988.	
		Zhang et al., Clinical Study on the Treatment of Acute Promyelocytic Leukemia with Ai Ling #1, J of Traditional Chinese and Western Medicine, Vol. 4, No. 1, 1984, p 19	
		Zhang et al., Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 Patients", J Harbin Medical University, Vol. 29, No. 3, 1995.	
		Zhang et al., Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology, Vol. 17, No. 2, 1996	

Examiner Signature:	Date Considered:
---------------------	------------------

\*EXAMINER: Initial if reference considered; whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.